



PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Fallaux et al.

Serial No.: 10/618,526

Filed: July 11, 2003

For: PACKAGING SYSTEMS FOR  
HUMAN RECOMBINANT ADENOVIRUS  
TO BE USED IN GENE THERAPY

Confirmation No.: 5055

Examiner: D. Nguyen

Group Art Unit: 1632

Attorney Docket No.: 2578-3833.9US

## DECLARATION

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I, Ronald Brus, hereby certify that I am the Chief Executive Officer of Crucell Holland BV ("Crucell") and declare that:

1. Crucell is the assignee of record of U.S. Patent Application Serial No. 10/618,526.
2. According to the deposit receipt, a deposit of the PER.C6 cell line was made, under ECACC deposit number 96022940, under the provisions of the Budapest Treaty with the Centre for Applied Microbiology and Research Authority (European Collection of Animal Cell

Serial No. 10/618,526

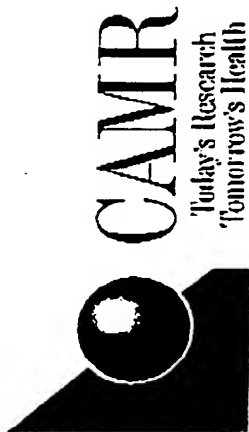
Cultures), Porton Down, Salisbury, Wiltshire SP4, OJG, United Kingdom, an International Depository Authority, on February 29, 1996.

3. On behalf of Crucell, I state that all restrictions upon public access to the deposit (except those permitted by 37 C.F.R. § 1.808(b)) will be irrevocably removed upon the grant of a U.S. patent on this U.S. patent application, and the deposit will be replaced if viable samples cannot be dispensed by the depository.

4. According to the deposit receipt, the deposit was accepted by the International Depository Authority, effective at least as early as February 29, 1996.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of the patent.

Date: February 23, 2005  
Dr. Ronald Brus



## Microbiological Research Authority

### Centre for Applied Microbiology and Research

This document certifies that CELL LINE  
(Deposit ref 96022940 ) has been accepted  
as a patent deposit, in accordance with

The Budapest Treaty of 1977,  
with the European Collection of Cell Cultures on

29th February 1996

*Dr. Alan Doyle,*  
Head, Cell Resources.

**BEST AVAILABLE COPY**

## APPENDIX 3

page 14

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO

INTROGENE BV  
PO Box 3271  
2280 GG Rijswijk  
The Netherlands  
NAME AND ADDRESS  
OF DEPOSITOR

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT  
issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this page

## I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the  
DEPOSITOR:

PER C6

Accession number given by the  
INTERNATIONAL DEPOSITARY AUTHORITY:

96022940

## II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

☒ a scientific description☐ a proposed taxonomic designation

(Mark with a cross where applicable)

## III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above,  
which was received by it on 29/2/1996 (date of the original deposit)<sup>1</sup>

## IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International  
Depositary Authority on (date of the original deposit) and  
a request to convert the original deposit to a deposit under the Budapest Treaty  
was received by it on (date of receipt of request for conversion)

## V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Dr A Doyle  
EMCAG, CAMR  
Porton Down  
Address: Millsbury SP4 0JC

Signature(s) of person(s) having the power  
to represent the International Depositary  
Authority or of authorized official(s):

Date: 27.2.97

<sup>1</sup> where Rule 6.4(d) applies, such date is the date on which the status of international depositary  
authority was acquired.

Appendix 3  
page 24BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSES OF PATENT PROCEDURE

## INTERNATIONAL FORM

TO  
INTROGENE BV  
PO Box 3271  
2280 GG Rijswijk  
The Netherlands

VIABILITY STATEMENT  
issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified on the following page

NAME AND ADDRESS OF THE PARTY  
TO WHOM THE VIABILITY STATEMENT  
IS ISSUED

I. DEPOSITOR.	II. IDENTIFICATION OF THE MICROORGANISM
Name: Introgene BV  Address: PO Box 3271 2280 GG Rijswijk The Netherlands	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: 96022940  Date of the deposit or of the transfer: 29th February 1996
III. VIABILITY STATEMENT	
The viability of the microorganism identified under II above was tested on <div data-bbox="66 1255 245 1314"><input checked="checked" type="checkbox"/> <sup>3</sup> viable</div> <div data-bbox="66 1339 386 1398"><input type="checkbox"/> <sup>3</sup> no longer viable</div>	

- <sup>1</sup> Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most recent relevant date (date of the new deposit or date of the transfer).
- <sup>2</sup> In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.
- <sup>3</sup> Mark with a cross the applicable box.

Appendix 3  
page 25IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED<sup>4</sup>

## V. INTERNATIONAL DEPOSITARY AUTHORITY

Name: Dr A Doyle

Address: ECACC, CAMR  
Porton Down  
Salisbury  
SP4 0JGSignature(s) of person(s) having the power  
to represent the International Depositary  
Authority or of authorized official(s):

Date:

27.2.97

<sup>4</sup> Fill in if the information has been requested and if the results of the test were negative.